510(k) Summary

K061878

E Surgical, LLC
1990 N. California Blvd., Suite 1040
Walnut Creek, CA 94596
925-280-8388 Phone
925-280-1788 Fax
Contact: Hans Richter

OCT 24 2006

I. Trade Name: E Surgical Coated Electrode:
Electrode, Coated Ball
Electrode, Coated Blade
Electrode, Coated Needle

II. Common Name: Active Electrode

III. Classification: 21 CFR 878.4400, Class II, Electrosurgical Cutting and Coagulation Accessory

IV. Product Code: GEI

V. Indications for Use

E Surgical Coated Electrodes are intended as an alternative to uncoated stainless steel electrodes or "non-stick" coated electrodes for use in conventional monopolar electrosurgical accessories. The Coated Electrodes are intended for use in situations where monopolar electrosurgical cutting and coagulation are normally used.

VI. Predicate Devices
a. Valleylab Edge™ Coated Electrodes, K962044
b. New Deantronics, Ltd. Disposable Hand Switching Pencil, K982742

VII. Device Description
The E Surgical coated electrodes are designed as a standard stainless steel active electrode with a non-stick coating to prevent tissue and char build-up on the electrode. Three models: ball, needle, and blade are included.

VIII. Summary of Technological Characteristics
The active electrodes are substantially equivalent to the New Deantronic electrodes in the disposable hand switching pencil, K982742, and the Valleylab Edge™ Coated Electrodes, K962044. The electrodes are a modification to the single-use electrodes of various tip configurations. A proprietary coating provides a non-stick surface for easier cleaning of eschar during use.

The electrodes are intended for use during monopolar electrosurgery. The electrodes fit in currently marketed electrosurgical pencils offered by New Deantronics and other manufacturers.

IX. Safety and Performance Data
a. Meets safety and performance requirements under ANSI/AAMI HF 18 Electrosurgical Devices.
b. Finished product non-stick coating was bent to 90 degrees ten times without visible cracking of the coating.
c. Cutting or coagulation is initiated immediately at both lower and higher power settings.
d. Easy to clean properties after use on tissue.
e. Materials used in the construction of the electrodes meet ISO 10993 Biocompatibility requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2006

E. Surgical, LLC
% L.W. Ward and Associates, Inc.
Mr. Lewis Ward
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K061878
Trade/Device Name: E Surgical, Electrodes, Coated
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 4, 2006
Received: October 10, 2006

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061878

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: E Surgical, Electrodes, Coated

Indications for Use:

E Surgical Coated Electrodes are intended as an alternative to uncoated stainless steel electrodes or "non-stick" coated electrodes for use in conventional monopolar electrosurgical accessories. The Coated Electrodes are intended for use in situations where monopolar electrosurgical cutting and coagulation are normally used.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061878